JAN 11 2001

K003972

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

December 20, 2000

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED Ghost II PTA Catheter; Unclassified

Predicate Devices: NuMED Ghost PTA Catheter

Device Description: The NuMED, Inc. Ghost II PTA catheter is a dual lumen catheter for use in PTA applications. The catheter has two distinct passages housed inside a single polymeric tubing. The catheter also features a molded proximal end bifurcate with two distinct luminal passages. The moon shaped inflation lumen terminates into a distally mounted polymeric balloon. The balloon is of the non-compliant variety. The balloon is designed to insert through the smallest possible introduction sleeve. The shaft size and the guidewire size remains constant at 5F and 0.035" throughout the entire Ghost II catheter line. The distal lumen terminates at the tip of the catheter and will accept a 0.035" guidewire throughout. The lumen has radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. The catheter is blue in color and the balloon material is clear. The catheter balloon diameter is stamped onto the Y connector and the inflation extension is labeled with balloon diameter x balloon length x introducer size x shaft size x usable length x guidewire size, and the catheter lot number. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches. The Ghost II catheter is available in standard diameters from 3mm to 12mm in standard lengths of 1.5cm to 10cm.

Biocompatibility Testing:

The materials used in the NuMED Ghost II PTA Catheter is the same as those used in our other PTA Catheters (510(k) #K931009) and PTV Catheters (510(k) #K991977) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.
Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use: This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

Comparison Information:

MODEL:	NUMED GHOST PTA	NUMED GHOST II PTA
Indications:	This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**	This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**
Introducer:	5Fr, 6Fr, 7Fr	5Fr, 6Fr, 7Fr, 8Fr
Shaft Size:	5.0Fr, 5.5Fr, 6.0Fr	5.0Fr
Guidewire Size:	0.035"	0.035"
Usable Length:	90cm	40cm, 75cm, 120cm, 150cm
Balloon Diameter:	4mm – 10mm	3mm – 10mm, 12mm
Balloon Length:	2.0cm – 10.0cm	1.5cm – 10cm
Materials:	Shaft: PES3 Balloon: Selar Image Band: Platinum	Shaft: PES3 Balloon: PES2 Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloon.	Dual Lumen construction with distally mounted non-compliant balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 2001

Ms. Nichelle Laflesh
Numed, Inc.
2880 Main St.
Hopkinton, NY 12965

Re: K003972
Trade Name: Numed Ghost II PTA Catheters
Regulatory Class: II (two)
Product Code: 74 LIT, 74 DQY
Dated: December 20, 2000
Received: December 22, 2000

Dear Ms. Laflesh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: **NuMED Ghost II PTA Catheter**

Indications For Use:

- This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003972